DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 17, 2014

Human Design Medical, LLC
C/O Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K140929
Trade/Device Name: Z1 CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Ventilator, Non-Continuous
Regulatory Class: II
Product Code: BZD
Dated: September 16, 2014
Received: September 17, 2014

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140929

Device Name
Z1 CPAP System

Indications for Use *(Describe)*
The Z1 CPAP System is a single patient reusable device that provides continuous positive airway pressure (CPAP) to support treatment of adults weighing over 66 lbs (30 kg) with obstructive sleep apnea.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Prepared in accordance with 21 CFR § 807.92

Date Summary Prepared: September 16, 2014

Submitter Information:

Company Name: Human Design Medical, LLC
Company Address: 119 Braintree Street, Unit 703
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Device Information:

Trade Name: Z1 CPAP System

Common Name: CPAP System

Classification Name: Non-Continuous (Respirator) Ventilator, 21 CFR § 868.5905

Device Class: Class II

Predicate Devices:

510(k) Number:	K121374
Manufacturer:	Human Design Medical, LLC
Product Name:	Z1 Blower
510(k) Number:	K063476
Manufacturer:	Breas Medical AB
Product Name:	iSleep 20i
510(k) Number:	K100121
Manufacturer:	AeioMed, Inc.
Product Name:	Model 300157

Device Description: The Z1 CPAP System provides continuous positive airway pressure to support the treatment of adults over 66 lbs (30 kg) with obstructive sleep apnea. The device is a non-critical care, reusable, single patient device for use in the

	home setting, and it is intended to be a prescription use only device. The Z1 CPAP System is a modified version of the Z1 Blower cleared in K121374. The modifications include: addition of an optional battery, addition of an APAP mode, addition of Bluetooth and a mobile app, addition of new user settings, and changes to firmware.
Intended Use:	Provides continuous positive airway pressure (CPAP) to support treatment of adults with obstructive sleep apnea.
Indications for Use:	The Z1 CPAP System is a single patient reusable device That provides continuous positive airway pressure (CPAP) To support treatment of adults weighing over 66 lbs (30 kg) with obstructive sleep apnea.
Technological Characteristics Compared to Predicate:	The Z1 CPAP System consists of the main flow generator and accessories. The Z1 CPAP System and the identified predicate devices have the same fundamental technological characteristic: Use of a pneumatic pump to deliver continuous positive airway pressure within a clinically indicated therapeutic pressure range. All four of the systems include a flow generator and a power adaptor. The Z1 CPAP System, the Breas iSleep 20i System and the AeioMed Model 300157 also include an air tube and battery while the Z1 Blower cleared in K121374 can only be operated using the power adaptor and the air tube must be purchased separately. All four of the systems have buttons and a status display that allow the user to control the system. Additionally, the Z1 CPAP System allows the user to interact with the system via a mobile application. This is an optional user convenience component that does not impact the safety or effectiveness of the treatment delivered. All four of the systems include a CPAP treatment mode with a ramp feature. The Z1 CPAP System, the Z1 Blower and the AeioMed Model 300157 include a ramp period up to 45 minutes while the Breas iSleep 20i System has a ramp period up to 60 minutes. This minor difference between the Z1 CPAP System and the Breas iSleep 20i System does not impact the substantial equivalence. All ramp features are identical between the Z1 Blower and the Z1 CPAP System. The Z1 CPAP System and the Breas iSleep 20i System

both include an APAP mode with an auto pressure setting algorithm. The Z1 employs the exact same software code for the APAP mode auto pressure setting algorithm as was cleared for the iSleep20i in K063476. Performance data is provided which shows that the performance of the Z1 CPAP System in the APAP mode is substantially equivalent to the predicate device.

All four of the systems include dynamic pressure control. The predicate systems have one fixed setting. The Z1 CPAP System has three user selectable settings (called Z-Breathe 1, 2 and 3). Performance data is provided which shows that all Z-Breathe settings are equivalent between the Z1 CPAP System and one of the identified predicate devices.

The pressure range for all four of the systems is 4-20 cmH20 in 0.5 cm H2O increments. The Z1 CPAP System, the Z1 Blower and the AeioMed Model 300157 include an automatic altitude adjustment for conditions up to 8,000 feet. The operating range and storage range for the Z1 CPAP System and the Z1 Blower are identical. All four systems allow data management functionality through an SD data card or memory card or through a USB port.

Both the Z1 CPAP System and one of the identified predicate devices use a lithium ion battery pack with 4 cells and a voltage of 14.4 volts. The battery longevity was measured to be 5-8 hours for the Z1 CPAP System depending upon the exact use conditions while it was measured to be 5-7 hours for the predicate. The environment of use for all four systems is the home while the Breas iSleep 20i System can also be used in a clinical setting.

Performance Testing:

Human Design Medical has performed the following performance testing to support the safety and effectiveness of the Z1 CPAP System:

Maximum temperature at the patient connection port under normal and single fault conditions was < 43 degrees C at a pressure setting of 20 cmH20;

Pressure stability under static long-term conditions was within ± 1.0 cmH2O of the set pressure of 10 cmH2O;

Short term static pressure accuracy: the actual pressure was within the specified tolerance of the set pressure for all pressure settings;

Dynamic pressure stability: the average peak-to-peak pressure deviation was ≤ the maximum limit established by Human Design Medical, for each pressure and breathe rate setting and was compared to a predicate device;

Maximum flow rate was ≥ minimum limit established by Human Design Medical for each pressure setting.

Acoustic noise testing found that the sound pressure level was 26dBA;

Testing of the battery was performed to verify the safety, performance and longevity of the battery accessory.

Ability of the system to detect air leaks: air leaks were detected within ±5 mmH20 of the specified air leak detection thresholds;

Volatile organic compounds: no volatile organic compounds were observed in the air output of the device above what was found in the ambient air;

Particulate matter: no particulate matter was observed in the output air of the device above what was found in the ambient air;

The Z1 Blower added no carbon monoxide or carbon dioxide to the output air and the ozone output of the device met the 21 CFR 801.415 requirement of 0.05 ppm or less.

Altitude testing showed that the Z1 maintained actual output pressure within the specified tolerance limits throughout the entire specified altitude pressure range of operation.

The pressure waveforms for the three z-Breathe settings have been compared with the pressure waveforms for the predicate device and it was determined that the performance was substantially equivalent.

The Z1 Blower complies with the following performance

and safety standards: ISO 5356-1:2004 Anesthetic and Respiratory Equipment – Conical Connectors: Part 1: Cones and Sockets. ASTM F 1246-91 standard specification for Electrically Powered Home Care Ventilators, Part 1 – Positive-Pressure Ventilators and Ventilator Circuits. IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility – requirements and tests. IEC 60601-1-6: Medical Electrical Equipment-Part 1-6: General requirements for basic safety and essential performance-collateral standard: Usability. IEC 60601-1-11 Medical Electrical Equipment-Part 1-11: General requirements for basic safety and essential performance-collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (including Technical Corridgendum 1).

ISO 23328-2:2002 Breathing system filters for anesthetic and respiratory use – part 2: non filtration aspects. ISO 17510-1:2007 Sleep apnoea breathing therapy– Part 1: Sleep apnoea breathing therapy equipment.

Biocompatibility testing was performed which showed that the patient contacting components of the system comply with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing; ISO 10993-3:2003 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity; ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity; ISO 10993-6:2007 Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation; ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization; and ISO 10993-12:2012 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

Testing of the CPAP Tube was performed which validated the recommended cleaning procedures and replacement interval.

The APAP software of the Z1 CPAP System is identical to the APAP software of the iSleep20i System cleared by FDA in K063476. The iSleep20i software source code, as well as the entire iSleep20i Design History File and Regulatory Master File were acquired by Human Design Medical as part of a business acquisition. Human Design Medical ported the iSleep20i APAP software into the Z1 CPAP System without modification. Therefore, the Z1 CPAP System employs the exact same software code as was cleared for the iSleep20i in K063476.

Since the APAP software has already been cleared in K063476 for the iSleep20i, it was only necessary to verify and validate that the Z1 CPAP System, when running the same software and presented with the same clinically diverse dataset on the bench, produces the same results as the iSleep20i System. Therefore Human Design Medical has conducted extensive bench testing of the Z1 CPAP System side-by-side with the iSleep20i System to verify and validate that the two devices produce the same respiratory event detections and pressure adjustment outputs for the same input air flow data. This testing is described in the following paragraph.

The same pneumatic air flow signals from a test lung were presented to the iSleep20i and the Z1. The test lung air flow signals comprised a clinically diverse data set of respiratory patterns, breathing rates, pressure settings, recovery to normal breathing and non-recovery patterns, etc. The therapy pressures generated by each device over time were compared. The pressure output of the Z1 matched the pressure output of the iSleep20i within the specified accuracy across all air flow signals within each sample time interval and met the acceptance criterion of matching within the specified accuracy. The outputs of ancillary algorithms for detecting apnea and hypopnea events were also compared. The number of apnea-hypopnea events detected by the two devices was the same, and met the acceptance criterion for an exact match. Additionally, software-level testing was performed in which the same digitized flow samples were presented to the iSleep20i and the Z1. The digitized flow data comprised a clinically diverse data set. The outputs of the software in each device were compared on a sample by sample basis and met all acceptance criteria for level of

	agreement. The results of the APAP testing satisfied each and every acceptance criterion of the V&V Plan without exception. No clinical data was generated to support a substantial equivalence determination. A determination was made that bench performance testing was appropriate versus clinical performance testing because there are accepted bench performance testing methodologies available which allow a direct comparison of the performance of the Z1 CPAP System compared to the predicate devices under a wide variety of operating conditions.
Conclusion:	The Z1 CPAP System is substantially equivalent to the predicate devices, as the devices share a common intended use, and technological differences between the Z1 CPAP System and the predicate do not raise new questions of safety or effectiveness.